PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Fernando DeCaprio, Jan Seppala and Raed Rizq**
Application No.:	**09/970459**
Filed:	**October 2, 2001**
For:	**STENT DELIVERY WITH MEMBRANE**
Examiner:	**Tan-Uyen Ho**
Group Art Unit:	**3731**
Firm Docket No.:	**S63.2R-9493-US02**

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Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

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Alexandria, VA 22313-1450

Docket No.: S63.2B-9493-US02

BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application in which claims 1-15 were finally rejected in an Office Action mailed December 3, 2004. A response to the Final Office Action was filed on February 4, 2005, and an Advisory Action was issued on February 17, 2005. A Notice of Appeal was filed in this case on April 4, 2005. This brief is submitted in accordance with 37 C.F.R. § 41.37:

> *(a)(1) Appellant must file a brief under this section within two months from the date of filing the notice of appeal under §41.31.*
>
> *(2) The brief must be accompanied by the fee set forth in §41.20(b)(2).*
>
> *(b) On failure to file the brief, accompanied by the requisite fee, within the period specified in paragraph (a) of this section, the appeal will stand dismissed.*

The fees required under § 41.20(b)(2) and any required petition for extension of time for filing this brief therefor are dealt with in the accompanying Transmittal Letter.

> *(c)(1) The brief shall contain the following items under appropriate headings and in the order indicated in paragraphs (c)(1)(i) through (c)(1)(x) of this section, except that a brief filed by an appellant who is not represented by a registered practitioner need only substantially comply with paragraphs (c)(1)(i) through (c)(1)(iv) and (c)(1)(vii) through (c)(1)(x) of this section:*

(i) Real Party in Interest

> *(i) Real party in interest. A statement identifying by name the real party in interest.*

The application is assigned to Boston Scientific Scimed, Inc., (former name: Scimed Life Systems, Inc.), SciMed Life Systems, Inc., One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

(ii) Related appeals and interferences. A statement identifying by application, patent, appeal or interference number all other prior and pending appeals, interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Copies of any decisions rendered by a court or the Board in any proceeding identified under this paragraph must be included in an appendix as required by paragraph (c)(1)(x) of this section.

No related appeals or interferences are pending.

(iii) Status of claims

(iii) Status of claims. A statement of the status of all the claims in the proceeding (e.g., rejected, allowed or confirmed, withdrawn, objected to, canceled) and an identification of those claims that are being appealed.

Claims 1-15 are shown to be pending and have been rejected. No claims have been allowed, withdrawn, canceled (See section iv) or objected to. The claims that are being appealed are 1-15.

(iv) Status of amendments

(iv) Status of amendments. A statement of the status of any amendment filed subsequent to final rejection.

As mentioned above, claims 1-15 are shown to be pending and have been rejected. However, in response to the Final Official Action, which was mailed on December 3, 2004, Applicant amended the claims by canceling claim 6 and by making a minor amendment to claim 7 on February 4, 2005. These amendments were not reflected in the Advisory Action, however, Applicant believes that these amendments were merely overlooked and will be entered for purposes of the appeal once they are brought to the Examiner's attention. As such, the listing of the claims in section viii reflects the amendments.

(v) Summary of claimed subject matter

(v) Summary of claimed subject matter. A concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which shall refer to the specification by page and line number, and to the drawing, if any, by reference characters. For each independent claim involved in the appeal and for each dependent claim argued separately under the provisions of paragraph (c)(1)(vii) of this section, every means plus function and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters.

Claims 1-15 pertain to a stent delivery catheter employing one or more socks or sleeves to retain the stent on the catheter. In addition, a unique membrane or stent covering is employed between the stent retaining sleeves to provide complete or selective coverage of the stent therebetween. The membrane of the present invention is sufficiently flexible to provide for adequate trackability of the catheter through the extremely tortuous confines of a body vessel. However, the membrane is of sufficient strength to prevent stent elements from lifting outward from the catheter surface thereby preventing such elements from interfering with a vessel wall during catheter advancement. Hereafter, the required references to the specification and drawings are provided in brackets in the claim summaries below.

According to independent claim 1, the stent delivery system [Page 10, lines 9-14] comprises a catheter having a balloon [Fig. 5, Item 14] mounted on its distal end. A stent [Figs. 1 and 5, Items 16, 18 and 20] having an unexpanded state and an expanded state is disposed about at least a portion of the balloon. The stent delivery system further includes at least one sleeve [Fig. 5, Items 22 or 24], wherein a portion or end of the at least one sleeve is engaged to at least a portion of the catheter shaft adjacent to the stent [Claim 1 as filed and Fig. 5] and a second portion or end at least partially overlaying an end of the stent when the stent is in the unexpanded state [Claim 1 as filed and Fig. 5]. The claim invention of claim 1 further comprises at least one membrane [Fig. 5, Item 26], wherein at least a portion of the membrane [Fig. 5, Item 26] is disposed beneath at least a portion of the at least one sleeve [Fig. 5, Item 18 or 20] and wherein the at least one membrane [Fig. 5, Item 26] is also disposed about at least a portion of the stent [Fig. 5, Item 16]. The at least one membrane [Fig. 5, Item 26] is constructed and arranged to prevent the at least a portion of the stent from flaring outward during advancement of the catheter through a vessel [Page 8, line 21, to page 9, line 18].

According to dependent claim 2, the at least one sleeve may further comprise a first sleeve [Fig. 5, Item 22] and a second sleeve [Fig. 5, Item 24] opposingly oriented [Fig. 5, Items 22 and 24], wherein the first and second sleeves cover at least part of the stent at its ends [Fig. 5, Items 18 and 20]

According to claim 3, the ends of the at least one membrane [Fig. 5, Item 26] may be covered by the first and second sleeves [Fig. 5, Items 22 and 24, and Page 10, lines 9-14].

According to claim 4, the at least one membrane may comprise a plurality of membranes spaced apart axially along the stent [Page 9, lines 10-18].

According to claims 7-8, the at least one membrane may be constructed and arranged to expand with the stent from its unexpanded state to the expanded state [Fig. 4 and page 9, line 26 to page 10, line 8] and the at least one membrane may be water soluble [Fig. 4 and page 9, line 26 to page 10, line 5].

According to claim 9, in addition to the invention claimed in claim 1, the at least one membrane may be a thermoplastic elastomer [Page 9, lines 1-4].

According to claim 10, in addition to the invention claimed in claim 1, the at least one membrane may be manufactured from at least one material selected from the group consisting of KRATON, polystyrene, polyurethanes and any combinations thereof [Page 9, lines 1-4] and, according to claim 11, it may be additionally manufactured from at least one material of the group consisting of polytetrafluoroethylene, siloxane, and any combinations thereof.

According to claim 12, in addition to the invention claimed in claim 1, the at least one membrane may be a drug delivery device [Fig. 4 and page 9, line 26 to page 10, line 5].

According to claim 13, the at least one membrane has a membrane thickness which is less than or equal to the thickness of the at least one sleeve [Page 8, lines 21-27 and claim 13 as filed]. In one embodiment the membrane thickness is less than 0.005 inches thick and in a further embodiment the membrane thickness is between about 0.004 and about 0.002 inches thick [Page 8, lines 21-27].

(vi) Grounds of Rejection to be Reviewed on Appeal

(vi) Grounds of rejection to be reviewed on appeal. A concise statement of each ground of rejection presented for review.

Ground I:

Review on appeal is requested of the Examiner's contention that claims 1-3 and 5-15 are obvious from Shull et al (US 6143022) in view of Savin et al (US 4950227).

Ground II:

Review on appeal is also requested of Examiner's contention that claim 4 is obvious from Herweck et al (US 6270523) in view of Savin et al (US 4950227).

(vii) Argument

(vii) Argument. The contentions of appellant with respect to each ground of rejection presented for review in paragraph (c)(1)(vi) of this section, and the basis therefor, with citations of the statutes, regulations, authorities, and parts of the record relied on. Any arguments or authorities not included in the brief or a reply brief filed pursuant to §41.41 will be refused consideration by the Board, unless good cause is shown. Each ground of rejection must be treated under a separate heading. For each ground of rejection applying to two or more claims, the claims may be argued separately or as a group. When multiple claims subject to the same ground of rejection are argued as a group by appellant, the Board may select a single claim from the group of claims that are argued together to decide the appeal with respect to the group of claims as to the ground of rejection on the basis of the selected claim alone. Notwithstanding any other provision of this paragraph, the failure of appellant to separately argue claims which appellant has grouped together shall constitute a waiver of any argument that the Board must consider the patentability of any grouped claim separately. Any claim argued separately should be placed under a subheading identifying the claim by number. Claims argued as a group should be placed under a subheading identifying the claims by number. A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.

Ground I. The Examiner Erred in rejecting Claims 1-3 and 5-15 as Obvious over Shull et al (US 6143022) in view of Savin et al (US 4950227).

In the Final Office Action, claims 1-3 and 5-15 were rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 6,143,022 ("Shull") in view of U.S. Patent No. 4,950,227 ("Savin"). In traversing the rejection below, Applicant considers claims 1-3, 5, 7, 9-11 and 13-15 to be grouped together, claim 8 to stand alone and claim 12 to stand alone. The groupings are indicated below and discussed separately. Claim 6 is considered to be canceled.

Claims 1-3, 5, 7, 9-11 and 13-15:

To support an obviousness rejection, the cited prior art must specifically suggest the combination as claimed, and it must be applied in the context of their significance to a technician at the time the invention was made, without knowledge of the solution. It is impermissible, simply to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the various documents to supply elements to fill the gaps. The cited documents themselves must provide some teaching whereby the applicant's combination would have been obvious, again at the time the invention was made. US patent law is replete with cases that illustrate this principle. *See e.g. In re Fine*, 37 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988); *In re Oetiker*, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992); *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992); *In re Kotzab*, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000); *WL. Gore & Associates v. Garlock, Inc.*, 721 F.2d. 1540, *1553*, 220 USPQ 303, 313 (Fed. Cir. 1983) and *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir.1999). The Examiner has not made the requisite showing.

The Examiner has admitted that Shull does not disclose or teach a stent mounted on a balloon catheter having sleeves, and looks to Savin for its disclosure of a balloon catheter with a stent mounted thereto and having sleeves for securing and maintaining a reduced diameter of a self-expanding stent on the balloon. However, Shull also fails to disclose a membrane which covers at least a portion of the stent to prevent flaring, as required by claim 1. The graft 20 of Shull has a completely different purpose than the problem being solved by the present invention. Shull discloses at Col. 1 line 60-65 that (emphasis added):

> Attempts to address these problems include providing a suitable surface within the lumen for more controlled healing to occur in addition to the support provided by a stent. These attempts include providing a lining or covering in conjunction with an implanted stent. A stent with such a lining or covering is known in the art as a stent-graft.

Therefore, it can be seen that Shull does not disclose or teach using a lining or covering to prevent flaring, as in the present invention.

As 35 U.S.C. §103 and the Federal Circuit make clear, when considering obviousness, **the Court must consider the claimed invention "as a whole"**. See *Ruiz v. A.B. Chance Co.*, 69 USPQ2d 1686, 357 F3d 1270 (Fed. Cir. 2004) in which the Federal Circuit stated (emphasis added):

> Section 103 of title 35 of the United States Code states:

> A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter **as a whole** would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. §103(a) (2000).
>
> In making the assessment of differences, section 103 specifically requires consideration of the claimed invention "as a whole." Inventions typically are new combinations of existing principles or features. Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693, 698 [218 USPQ 865] (Fed. Cir. 1983) (noting that "virtually all [inventions] are combinations of old elements."). **The "as a whole" instruction in title 35 prevents evaluation of the invention part by part.** Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of **hindsight** reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result – often the very definition of invention.
>
> Section 103 precludes this **hindsight** discounting of the value of new combinations by requiring assessment of the invention as a whole. This court has provided further assurance of an "as a whole" assessment of the invention under §103 **by requiring a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner.** In other words, the examiner or court must show some suggestion or motivation, before the invention itself, to make the new combination. See In re Rouffet, 149 F.3d 1350, 1355-56 [47 USPQ2d 1453] (Fed. Cir. 1998).

The Federal Circuit also discussed hindsight as follows:

> ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."). In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002).

In order to combat impermissible hindsight, the Federal Circuit has also made it clear that the showing of a **motivation** to combine two or more references must be **"clear and particular"**. See for example *Winner International Royalty Corp. v. Wang*, 53 USPQ2d 1580, 202 F3d 1340 (Fed. Cir. 2000), where the Federal Circuit stated (emphasis added):

> When an obviousness determination is based on multiple prior art references, there must be a showing of some "teaching, suggestion, or reason" to combine the references. [Citation omitted].
> ...
> Although a reference need not expressly teach that the disclosure contained therein should be combined with another, [citation omitted] the showing of combinability, in whatever form, must nevertheless be **"clear and particular."**

As the Federal Circuit also stated:

> "The factual inquiry whether to combine references must be **thorough and searching."** Id. It must be based on **objective evidence of record.** This precedent has been reinforced in myriad decisions, and cannot be dispensed with. (Emphasis added). In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002).

Applicant respectfully submits that the Examiner has not met the burden of showing a "clear and particular" motivation to combine Shull and Savin. One of ordinary skill in the art would have no reason, other than impermissible hindsight, to combine the teachings of Shull and Savin. Shull is totally and completely silent on using sleeves to hold the stent in place during deployment and Savin is completely silent on using a membrane to cover the stent to prevent flaring. Only by looking at the prior art through the lens of the present invention, by using impermissible hindsight, can the Examiner combine these two references. There is no objective evidence of record which would motivate or suggest to one of ordinary skill in the art to combine Shull and Savin.

In addition, the graft of Shull is longer than the stent, when the stent is in its contracted state, as shown in Figure 6. The ends of the graft are folded over the ends of the stent and under the stent wall, as shown in Figures 2 and 7. As the stent expands, it unfolds from under the stent wall and foreshortens, resulting in the configuration shown in Figure 3. Due to the thinness of the graft (Col. 6, lines 49-50) and the requirement that the graft be "sufficiently free during deployment of the device to achieve a desired configuration of the graft component with respect to the stent" (Col. 4, lines 58-60), it would not have been obvious to impede the graft material during its foreshortening during expansion of the stent by covering the graft with retaining sleeves, as suggested by the Examiner.

The Examiner cites *In re Fine*, arguing that a prima facie case of obviousness has been established from "generally available knowledge that would lead one skilled in the art to combine teachings of existing references." The Examiner argues that one of ordinary skill in the art would combine sleeves with a membrane because together they would secure the stent to the delivery system and maintain a reduced diameter. The Examiner has, however, failed to provide any "clear and particular" motivation to combine the reference, as required by the Federal Circuit in *Winner International Royalty Corp.* "The showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence." *Teleflex, Inc. v. Ficosa North America Corp.*, (Fed. Cir. 2002, *en banc)* 299 F.3d 1313, 63 U.S.P.Q.2d 1374. The actual evidence must be "objective evidence of record." *In re* Lee, 277 F.3d 1338, 61 USPQ2d 1340. Merely asserting that a particular combination of elements from prior art references can be

combined to produce the present invention does not provide the required "clear and particular" motivation necessary to support an obviousness rejection.

Applicants respectfully submit that the Examiner has failed to meet the burden set forth under *Winner International Royalty Corp* and therefore respectfully traverse the rejections of claims 1-3, 5, 7, 9-11, and 13-15.

Claim 8:

Claim 8 depends from nonobvious dependent claim 7, which depends from nonobvious independent claim 1 and is separately patentable over claims 1 and 7. For at least the reasons presented above with regard to claims 1-3, 5, 7, 9-11, and 13-15, claim 8 is nonobvious. Also, claim 8 includes a further limitation that "the at least one membrane is water soluble." The Examiner fails to provide any reference to support the assertion that stent coverings that include a water-soluble drug are well-known in the art. Therefore, Applicants request that the rejection be overturned.

Claim 12:

Claim 12 is separately patentable over the other claims. As stated in the Final Office Action in paragraph 2, the Examiner admits that Shull fails to disclose a catheter having sleeves for delivering a stent. The Examiner uses the Savin reference to provide disclosure for a stent delivering system including sleeves for securing and maintaining a reduced diameter of a self-expanding stent on a balloon for delivering to a deployment site. As argued above with regard to claims 1-3, 5, 7, 9-11, and 13-15, claim 12 is nonobvious because there is no teaching, suggestion, or motivation to combine Shull with Savin or Savin with Shull to produce a device with both at least one sleeve and at least one membrane. Furthermore, there is no cited teaching, suggestion, or motivation to use at least one membrane as a drug delivery device, a further limitation provided in claim 12. It is impermissible to use hindsight, rather than a teaching,

suggestion, or motivation, to modify references for the purpose of rejecting as obvious under 35 U.S.C. § 103. The Examiner has failed to provide any "clear and particular" motivation to combine the reference, as required by the Federal Circuit in *Winner International Royalty Corp.* Therefore, Applicants respectfully request that the rejection be overturned.

Ground II. The Examiner Erred in rejecting Claim 4 as Obvious over U.S. Patent No. *6,270,523* ("Herweck") in view of Savin.

In the Final Office Action in paragraph 4, claim 4 was rejected under 35 U.S.C. 103 as being unpatentable over Herwick in view of Savin. The Examiner admits that Herwick fails to disclose a catheter having sleeves for delivering a stent. The Examiner uses the Savin reference to provide a disclosure for a stent delivery system including sleeves for securing and maintaining a reduced diameter of a self-expanding stent on a balloon. However, this combination is improper because there is no suggestion or motivation to combine Herwick with Savin. Furthermore, the Herwick reference teaches away from the present invention. While the membrane of the present invention is used to prevent flaring (page 9, lines *15-18),* Herwick is used to create flaring. (Herwick, col. 6, lines 28-33). Therefore, one of ordinary skill in the art would not look to Herwick to solve the problem of flaring, as accomplished by the present invention.

The Herwick reference teaches using membranes of varying resistances in order to prevent the expansion of portions of a stent. (Herwick, col. 6, lines *15-17).* Sleeves, on the other hand, are used in order to control delivery of a stent. That is, when the stent delivery system is in place, the sleeves retract, thereby allowing the stent to expand. One of ordinary skill in the art would not combine Herwick, which seeks to prevent expansion of portions the stent, with the sleeves of Savin, which seek to allow expansion of the entire stent upon their retraction.

As such, the Examiner has not identified a reasonable motivation to combine the Herwick and Savin patents to make the invention of claim 4 obvious. Reversal of the rejection under 35 USC §103 is therefore respectfully requested.

The Board is respectfully requested to reverse the rejections with instruction to pass the application to issue.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: June 21, 2005

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(viii) Claims Appendix

(viii) Claims appendix. An appendix containing a copy of the claims involved in the appeal.

1. (Previously presented) A stent delivery system comprising:

a catheter, the catheter having a catheter shaft, the catheter shaft having a balloon mounted thereto;

a stent, the stent disposed about at least a portion of the balloon, the stent having an unexpanded state and an expanded state;

at least one sleeve, the at least one sleeve having a first portion and a second portion, the first portion being engaged to at least a portion of the catheter shaft adjacent to the stent, the second portion at least partially overlaying an end of the stent when the stent is in the unexpanded state;

at least one membrane, at least a portion of the membrane disposed beneath at least a portion of the at least one sleeve, the at least one membrane disposed about at least a portion of the stent, the at least one membrane constructed and arranged to prevent the at least a portion of the stent from flaring outward during advancement of the catheter through a vessel.

2. (Original) The stent delivery system of claim 1 wherein the at least one sleeve further comprises a first sleeve and a second sleeve, the stent further comprising a first end and a second end, the second portion of the first sleeve at least partially overlapping the first end of the stent, and the second portion of the second sleeve at least partially overlapping the second end of the stent.

3. (Original) The stent delivery system of claim 2 wherein the at least one membrane is disposed about at least a portion of the stent positioned between the second portion of the first sleeve and the second portion of the second sleeve.

4. (Original) The stent delivery system of claim 2 wherein the at least one membrane is a plurality of membranes spaced apart axially along the stent.

5. (Previously presented) The stent delivery system of claim 2 wherein the second portion of the first sleeve and the second portion of the second sleeve respectively overlying at least a portion of the at least one membrane and an end of the stent.

6. (Cancelled)

7. (Previously presented) The stent delivery system of claim 1 wherein the at least one membrane is further constructed and arranged to expand with the stent from the unexpanded state to the expanded state.

8. (Original) The stent delivery system of claim 7 wherein the at least one membrane is water soluble.

9. (Previously presented) A stent delivery system comprising:

a catheter, the catheter having a catheter shaft, the catheter shaft having a balloon mounted thereto;

a stent, the stent disposed about at least a portion of the balloon, the stent having an unexpanded state and an expanded state;

at least one sleeve, the at least one sleeve having a first portion and a second portion, the first portion being engaged to at least a portion of the catheter shaft adjacent to the stent, the second portion at least partially overlaying an end of the stent when the stent is in the unexpanded state;

at least one membrane, the at least one membrane disposed about at least a portion of the stent, the at least one membrane constructed and arranged to prevent the at least a portion of the stent from flaring outward during advancement of the catheter through a vessel;

wherein the at least one membrane is a thermoplastic elastomer.

10. (Previously presented) A stent delivery system comprising:

a catheter, the catheter having a catheter shaft, the catheter shaft having a balloon mounted thereto;

a stent, the stent disposed about at least a portion of the balloon, the stent having an unexpanded state and an expanded state;

at least one sleeve, the at least one sleeve having a first portion and a second portion, the first portion being engaged to at least a portion of the catheter shaft adjacent to the stent, the second portion at least partially overlaying an end of the stent when the stent is in the unexpanded state;

at least one membrane, the at least one membrane disposed about at least a portion of the stent, the at least one membrane constructed and arranged to prevent the at least a portion of the

stent from flaring outward during advancement of the catheter through a vessel;

wherein the at least one membrane is manufactured from at least one material selected from the group consisting of KRATON, polystyrene, polyurethanes and any combinations thereof.

11.(Original) The stent delivery system of claim 10 where in the at least one membrane is additionally manufactured from at least one material of the group consisting of polytetrafluoroethylene, siloxane, and any combinations thereof.

12.(Previously presented) A stent delivery system comprising:

a catheter, the catheter having a catheter shaft, the catheter shaft having a balloon mounted thereto;

a stent, the stent disposed about at least a portion of the balloon, the stent having an unexpanded state and an expanded state;

at least one sleeve, the at least one sleeve having a first portion and a second portion, the first portion being engaged to at least a portion of the catheter shaft adjacent to the stent, the second portion at least partially overlaying an end of the stent when the stent is in the unexpanded state;

at least one membrane, the at least one membrane disposed about at least a portion of the stent, the at least one membrane constructed and arranged to prevent the at least a portion of the stent from flaring outward during advancement of the catheter through a vessel;

wherein the at least one membrane is a drug delivery device.

13.(Original) The stent delivery system of claim 1 wherein the at least one membrane has a predetermined membrane thickness and the at least one sleeve has a predetermined sleeve thickness, the predetermined membrane thickness being less than or equal to the predetermined sleeve thickness.

14.(Previously presented) A stent delivery system comprising:

a catheter, the catheter having a catheter shaft, the catheter shaft having a balloon mounted thereto;

a stent, the stent disposed about at least a portion of the balloon, the stent having an unexpanded state and an expanded state;

at least one sleeve, the at least one sleeve having a first portion and a second portion, the first portion being engaged to at least a portion of the catheter shaft adjacent to the stent, the second portion at least partially overlaying an end of the stent when the stent is in the unexpanded state;

at least one membrane, the at least one membrane disposed about at least a portion of the stent, the at least one membrane constructed and arranged to prevent the at least a portion of the stent from flaring outward during advancement of the catheter through a vessel;

wherein the at least one membrane has a predetermined membrane thickness and the at least one sleeve has a predetermined sleeve thickness, the predetermined membrane thickness being less than or equal to the predetermined sleeve thickness;

wherein the predetermined membrane thickness is less than 0.005 inches thick.

15. (Original) The stent delivery device of claim 14 wherein the predetermined membrane thickness is between about 0.004 and about 0.002 inches thick.

1. *(ix) Evidence appendix. An appendix containing copies of any evidence submitted pursuant to §§1.130, 1.131, or 1.132 of this title or of any other evidence entered by the examiner and relied upon by appellant in the appeal, along with a statement setting forth where in the record that evidence was entered in the record by the examiner. Reference to unentered evidence is not permitted in the brief. See §41.33 for treatment of evidence submitted after appeal. This appendix may also include copies of the evidence relied upon by the examiner as to grounds of rejection to be reviewed on appeal.*

Not applicable

(x) Related proceedings appendix. An appendix containing copies of decisions rendered by a court or the Board in any proceeding identified pursuant to paragraph (c)(1)(ii) of this section.

Not applicable

(2) A brief shall not include any new or non-admitted amendment, or any new or non-admitted affidavit or other evidence. See §1.116 of this title for amendments, affidavits or other evidence filed after final action but before or on the same date of filing an appeal and §41.33 for amendments, affidavits or other evidence filed after the date of filing the appeal.

(d) If a brief is filed which does not comply with all the requirements of paragraph (c) of this section, appellant will be notified of the reasons for non-compliance and given a time period within which to file an amended brief. If appellant does not file an amended brief within the set time period, or files an amended brief which does not overcome all the reasons for non-compliance stated in the notification, the appeal will stand dismissed.

(e) The time periods set forth in this section are extendable under the provisions of §1.136 of this title for patent applications and §1.550(c) of this title for ex parte reexamination proceedings.